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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 11/14/2001 Barbara Sheila Goldberg 1223.0050000 7303 09/936,608 EXAMINER 7590 11/01/2005 William J Sapone PRUNNER, KATHLEEN J Coleman Sudol Sapone P C PAPER NUMBER ART UNIT 714 Colorado Avenue Bridgeport, CT 06605 3751

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)		
Office Action Comments	09/936,608	GOLDBERG ET AL.		
Office Action Summary	Examiner	Art Unit		
	Kathleen J. Prunner	3751		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
Status				
1) Responsive to communication(s) filed on 14 Fe	ebruary 2005.			
2a)⊠ This action is <b>FINAL</b> . 2b)□ This action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims				
4) Claim(s) 15-42 is/are pending in the application.				
4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) <u>15-42</u> is/are rejected.  7) Claim(s) is/are objected to.				
8) Claim(s) are subject to restriction and/or	r election requirement.			
Application Papers				
<ul> <li>9) ☐ The specification is objected to by the Examiner.</li> <li>10) ☐ The drawing(s) filed on <u>02 August 2004</u> is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>				
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for foreign  a) All b) Some * c) None of:  1. Certified copies of the priority documents  2. Certified copies of the priority documents  3. Copies of the certified copies of the priority application from the International Bureau	s have been received. s have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage		
* See the attached detailed Office action for a list  Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4)	(PTO-413)		

#### **DETAILED ACTION**

### **Drawings**

- 1. The new formal drawings were received on August 2, 2004. These drawings are approved.
- 2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, (A) "an area to be treated", as called for by claim 15; (B) "an adhesive" on the first surface, as called for by claim 15; (C) "an area adjacent the area to be treated", as called for by claim 15, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) **mentioned** in the description: **26B** (note line 8 of the third full paragraph on page 5 as amended in the amendment filed January 8, 2003). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office

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action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one

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figure is being amended. Each drawing sheet submitted after the filing date of an application

must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37

CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the

drawings will not be held in abeyance.

4. In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is

required to submit a marked-up copy of each Replacement Sheet including annotations

indicating the changes made to the previous version. The marked-up copy must be clearly

labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that

explains the change(s) to the drawings. See 37 CFR 1.121(d)(1). Failure to timely submit the

proposed drawing and marked-up copy will result in the abandonment of the application.

Specification

5. The specification is objected to as failing to provide proper antecedent basis for the

claimed terminology. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The claim terminology

which lacks such antecedent basis is as follows: (A) a patch having "a first surface", as called

for by claims 15, 29, 41 and 42; (B) "an area adjacent the area to be treated", as called for by

claims 15, 41 and 42; and (C) "a closed dispensing container", as called for by claim 42.

Correction is required.

6. The following informalities in the specification are noted: (A) on page 5, line 18,

--substance or-- should be inserted after "suitable". Appropriate correction is required.

7. The following informalities in the claims are noted: (A) in claim 41, on line 15, --and--

should be inserted after the semicolon; (B) in claim 41, on line 17, --backing-- should be inserted

after "peelable"; (C) in claim 42, on line 11, --and-- should be inserted after the semicolon; and

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(D) in claim 42, on line 13, --backing-- should be inserted after "peelable". Appropriate

correction is required.

## Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 9. Claims 15-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 15, 29, 41 and 42 call for "a dispensing container". However, the originally filed disclosure fails to support or describe such a dispensing container or what structure (or material or acts) corresponds to this dispensing container.
- 10. Claims 15-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 15, 29, 41 and 42 call for "a removable release means". However, the originally filed disclosure fails to support or describe such a removable release means or what structure (or material or acts) corresponds to this means.
- Claims 25, 26, 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 25 and 37 call for the "release means" to have "means for removing a portion of the dispensing container". Claims 26 and 38 call for "the removing means".

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However, the originally filed disclosure fails to support or describe that the "release means has means for removing", "means for removing" and "removing means" or what structure (or material or acts) corresponds to such means.

- 12. Claims 15-42 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 15, 29, 41 and 42 call for "applicator means". However, the originally filed disclosure fails to support or describe such an applicator means or what structure (or material or acts) corresponds to this means.
- 13. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 29, from which claim 33 depends, is drawn to the second embodiment of the invention shown in Fig. 5. However, claim 33 is drawn to the first embodiment of the invention shown in Fig. 1 in which the sachet 14 has apertures 34. Therefore, the originally filed disclosure fails to provide support for or describe that the second embodiment sachet 62 can incorporate the apertures as shown in the first embodiment sachet 14.
- 14. Claims 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 41 calls for "a method for making an adhesive dispensing arrangement" comprising the steps of "providing a patch ...", "applying an adhesive ...", "providing a dispensing container ...", "filling the dispensing container ...", "mounting the applicator means ...", "providing container ...", "providing applicator means ...", "mounting the applicator means ...", "providing

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removable release means for opening ...", "placing the removable release means ...", and "covering the applicator means ...". Claim 42 calls for "a method for making an adhesive dispensing arrangement" comprising the steps of "providing a patch ...", "applying an adhesive ...", "providing a dispensing container ...", "mounting the ... dispensing container ...", "providing removable release means for opening ...", "placing the removable release means ...", and "covering the applicator means ...". However, the originally filed disclosure fails to support or describe such methods for making an adhesive dispensing arrangement. Hence, claims 41 and 42 are directed to new matter.

- 15. Claim 42 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "gauze pad 64 is typically impregnated with the substance to be dispensed" (note lines 13-14 on page 9), does not reasonably provide enablement for "substance containing applicator means therein", as called for on lines 5-6 and 8-9 of claim 42, and "the substance containing applicator means", as called for on lines 13-14 of claim 42. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with this claim.
- 16. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 17. The following is a quotation of the sixth paragraph of 35 U.S.C. 112:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

- 18. Claims 15-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 19. Regarding claims 29 and 42, the word "means" is preceded by the word "applicator" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means", it

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is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

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- 20. Claims 15 and 41 recite "applicator means ... for applying the substance". However, the specification fails to describe what structure (or material or acts) corresponds to this means.
- 21. Claims 15, 41 and 42 recite "removable release means located at least partially between the dispensing container and the applicator means for opening the dispensing container". However, the specification fails to describe what structure (or material or acts) corresponds to this removable release means.
- 22. Claim 29 recites "removable release means ... for exposing the applicator means". However, the specification fails to describe what structure (or material or acts) corresponds to this removable release means.
- 23. Claims 25 and 37 recite "the release means has 'means for removing a portion of the dispensing container". Claims 26 and 38 recite "the removing means". However, the specification fails to describe what structure (or material or acts) corresponds to this removing means.
- 24. Claim 39 contains a term lacking proper antecedent basis. The claim recites the limitation "the removable release means bonded to an upper portion of the dispensing container" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

### Claim Rejections - 35 USC § 102

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 26. Claims 29, 31-38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamaguchi et al. (EP 734,722). Yamaguchi et al. disclose an adhesive dispensing arrangement having all the claimed features including a patch 1 having a first surface (constituted by layer 5,

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note Fig. 1(a)) for covering the area to be treated (note lines 31-35 in col. 7 and lines 16-21 in col. 9), the first surface having an adhesive (constituted by the adhesive on layer 5) on at least a portion thereof; a dispensing container (constituted by the hollow in layer 2, note lines 50-51 in col. 3) for holding a substance containing applicator means (constituted by the drug storage layer 4) mounted therein, the dispensing container being retained on a portion of the first surface 5 (note Figs. 1 and 5-8); removable release means (constituted by the protective film 3, note Fig. 1(a)) located to at least partially overlie the dispensing container containing the applicator means (note Fig. 1(a)), for exposing the applicator means (note Fig. 1(b)) and releasing the contained substance; and a peelable backing (constituted by releasable liner layer 6) for covering the dispensing container, release means 3 and the first surface 5 (note Figs. 1(a), 1(b) and 5-7), such that removing the peelable backing 6 enables removal of the release means 3 (note Fig. 1(b)) for allowing the substance containing applicator means to be exposed (note Fig. 1(a)), for application to the area to be treated. With respect to claim 31, Yamaguchi et al. also disclose that the removable release means 3 has at least one portion engaged to the peelable backing 6 for co-removal therewith (note Fig. 1(b)). With respect to claim 32, Yamaguchi et al. further disclose that the release means 3 has two portions (constituted by the left and right sides of the cross-section shown in Fig. 2(a)) adhesively secured to the peelable backing 6 for co-removal therewith (note Fig. 1(b)). With respect to claim 33, Yamaguchi et al. additionally disclose that the dispensing container has at least one aperture, i.e., constituted by the open end of the hollow in layer 2 (note Fig. 1(b)), the removable release means 3 seals the aperture (note Fig. 1(a) and lines 16-19 in col. 7) and the removal of the removable release means 3 exposes the aperture and the substance containing applicator means within the dispensing container (note Fig. 1(b)). With regard to claim 34, Yamaguchi et al. also disclose that the removable release means 3 is a sealing strip (note lines 42-49 in col. 5). With regard to claim 35, Yamaguchi et al. further disclose that the substance is a medicament (note lines 25-59 in col. 4). With respect to claim 36, Yamaguchi et al. additionally disclose that the substance is a chemical treatment or catalyst (note lines 25-59 in col. 4). With regard to claim 37, Yamaguchi et al. also disclose that the release means 3 has Art Unit: 3751

means for removing (constituted by notches 7, note lines 7-9 in col. 6) a portion of the dispensing container to expose the substance containing applicator means therein (note Fig. 1(b), lines 42-48 in col. 6). With respect to claim 38, Yamaguchi et al. further disclose that the removing means comprises an adhesive for bonding the release means 3 to the portion of the dispensing container (note lines 48-50 in col. 6) such that removal of the release means 3 tears away the portion of the dispensing container (note Fig. 1(b) and lines 42-48 in col. 6). With respect to claim 40, it is considered that the dispensing container as shown in Fig. 1a of Yamaguchi et al. constitutes a sachet or packet since such drug patches are characteristically small.

27. Claim 42 is rejected under 35 U.S.C. 102(b) as being anticipated by Yamaguchi et al. (EP 734,722). Yamaguchi et al. disclose a method for making an adhesive dispensing arrangement comprising the steps of providing a patch having a first surface for covering an area (of the skin) to be treated (note from lines 54-59 in col. 6), applying an adhesive to the first surface on at least a portion thereof (note lines 54-56 in col. 6 and lines 40-42 in col. 10) for allowing the patch to stick to an area adjacent the area to be treated (note lines 31-35 in col. 7), providing a closed dispensing container containing substance containing applicator means therein (note lines 4-23 in col. 11), mounting the dispensing container onto a portion of the first surface (note lines 19-23 in col. 11), providing removable release means for opening the dispensing container to expose the substance containing applicator means therein (note lines 16-20 and 25-35 in col. 7), placing the removable release means over the dispensing container and at least a portion of the first surface (note lines 19-23 in col. 11), and covering the release means and the first surface with a peelable backing (note lines 42-45 in col. 5) such that removing the peelable backing enables removal of the release means for allowing the substance containing applicator means to be exposed for application to the area to be treated (note lines 25-35 in col. 7).

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### Claim Rejections - 35 USC § 103

28. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 30. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi et al. (EP 734,722) in view of Konishi. With regard to claim 30, although Yamaguchi et al. fail to disclose that the applicator means includes an absorbent pad, attention is directed to Konishi who discloses another patch/bandage that uses an applicator which includes at least one absorbent pad 2 (note lines 8-10 in col. 3) secured to the patch 11 (note Fig. 2) along at least one marginal adhering zone with a non-adhering zone (constituted by the top surface thereof as shown in Fig. 2) being disposed to at least partially overlie the dispensing container 6 in order to provide a

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patch/bandage in which the medicine maintains its effect for a prolonged period for achieving any desired sterilizing, disinfecting and curing purposes (note lines 37-40 in col. 1 and lines 36-38 in col. 3) and which can be applied without hurting or giving rise to pain (note lines 34-36 in col. 1). It would have been obvious to one of ordinary skill in the patch/bandage art, at the time the invention was made, to form the applicator of Yamaguchi et al. with an absorbent pad in view of the teachings of Konishi in order to allow the medication/drug to have a longer residence time in contact with the area to be treated as well as a more cushioning effect over that area for protection.

32. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi et al. (EP 734,722) in view of O'Reilly et al. It is considered that the dispensing container or the drug storage layer 4 of Yamaguchi et al. constitutes a sachet since it is a separate component of the patch (note lines 13-15 in col. 4). Although Yamaguchi et al. fail to disclose that the dispensing container or sachet has a weakened zone about a periphery or perimeter thereof, attention is directed to O'Reilly et al. who disclose another dispensing container or sachet (note lines 4-22 in col. 1) that is provided with weakening in the peripheral or perimeter seals (note lines 4-10 and 60-61 in col. 2) in order to provide outlets for the fluent medium or contents contained in the dispensing container or sachet (note lines 60-62 in col. 2). It would have been obvious to one of ordinary skill in the dispensing container or sachet art, at the time the invention was made, to form the dispensing container or sachet of Yamaguchi et al. with a weakened zone about a periphery or perimeter thereof in view of the teachings of O'Reilly et al. in order to provide outlets for the fluent medium or contents contained in the dispensing container or sachet such that the fluent medium or contents is distributed in a more controlled manner.

### Response to Arguments

33. Applicants' arguments filed August 2, 2004 with respect to the new claims have been considered but are most in view of the new ground(s) of rejection.

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34. Contrary to applicants' arguments with respect to the Yamaguchi reference and its patch,

the patch of this particular reference is constituted by the entire structure shown in Fig. 1(a) of

the reference (note lines 20-37 in col. 3) and not just one particular portion such as the backing

layer 2.

35. Applicants assert that the Yamaguchi reference has no dispensing container. However,

since applicants' originally filed disclosure fails to support or describe such a dispensing

container or state what structure (or material or acts) corresponds to this dispensing container, it

is considered that the hollow in layer 2 in the Yamaguchi reference constitutes such a dispensing

container since this hollow holds or contains a drug applicator in the form of storage layer 4.

Conclusion

36. Applicant's amendment necessitated the new ground(s) of rejection presented in this

Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this

final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Examiner Kathleen J. Prunner whose telephone number is 571-

272-4894.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu, can be reached on 571-272-4835. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

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Kathleen J. Prunner

October 19, 2005